

EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer: Roche Diagnostics GmbH
Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number: DE-MF-000006260

Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 125 II	11776223190	7613336001369X
Elecsys CA 125 II	11776223214	761333602082AF

Intended Use:

Immunoassay for the in vitro quantitative determination of OC 125 reactive determinants in human serum and plasma. These determinants are associated with a high molecular weight glycoprotein in serum and plasma of women with primary epithelial invasive ovarian cancer (excluding those with cancer of low malignant potential). This assay is indicated for use as an aid in the detection of residual or recurrent ovarian carcinoma in patients who have undergone first-line therapy and would be considered for second-look procedures. This assay is further indicated for serial measurement of CA 125 to aid in the management of cancer patients. This assay is also intended to be used in conjunction with the Elecsys HE4 assay as part of ROMA (Risk Of Ovarian Malignancy Algorithm) for the risk assessment of ovarian cancer in premenopausal and postmenopausal women presenting with pelvic mass.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 125 II	07026986190	761333600245A5
Elecsys CA 125 II	07026986214	761333602048AF
Elecsys CA 125 II	09755586190	761333602864BM

Intended Use:

Immunoassay for the in vitro quantitative determination of OC 125 reactive determinants in human serum and plasma. These determinants are associated with a high molecular weight glycoprotein in serum and plasma of women with primary epithelial invasive ovarian cancer (excluding those with cancer of low malignant potential). This assay is indicated for use as an aid in the detection of residual or recurrent ovarian carcinoma in patients who have undergone first-line therapy and would be considered for second-look procedures. This assay is further indicated for serial measurement of CA 125 to aid in the management of cancer patients. This assay is also intended to be used in conjunction with the Elecsys HE4 assay as part of ROMA (Risk Of Ovarian Malignancy Algorithm) for the risk assessment of ovarian cancer in pre- and postmenopausal women presenting with pelvic mass.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
CA 125 II CalSet II	07030207190	761333600406A5

Intended Use:

CA 125 II CalSet II is used for calibrating the quantitative Elecsys CA 125 II assay on cobas e immunoassay analyzers.

Risk Class:

A B C D

Conformity Route:

- Self-Declaration of Conformity (Class A)*
- Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)*
- Technical Documentation Assessment Class B/C – Annex IX*
- Technical Documentation Assessment Class D – Annex IX*
- Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX*
- Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX*
- Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX*

Certificates:

- EU QM Certificate No.: V12 010283 0639*
- EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):*

Other:

Common Specifications:

Notified Body (NB) Name:

TÜV Süd Product Service GmbH

NB Address:

Ridlerstraße 65

80339 Munich

Germany

0123

NB Ident. No.:

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 1 February 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

Christina Schmid

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Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

DocuSigned by:

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